

§ 124.510

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the annual compliance level, an explanation of why the facility did not meet the required level. If the facility claims that it failed to meet the required compliance level because it was financially unable to do so, it shall explain and provide documentation prescribed by the Secretary;

(iv) If the facility is required to submit an affirmative action plan, a copy of the plan.

(v) Other information that the Secretary prescribes.

(3) *Institution of suit.* Not later than 10 days after being served with a summons or complaint the facility shall notify the HHS Regional Health Administrator¹ for the Region in which it is located of any legal action brought against it alleging that it has failed to comply with the requirements of this subpart.

(b) *Facilities certified under § 124.513 or § 124.516.* A facility certified under § 124.513 or § 124.516 shall comply with paragraph (a)(3) of this section and shall submit within 90 days after the close of its fiscal year, as appropriate:

(1) A certification, signed by the responsible official of the facility, that there has been no material change in the factors upon which the certification was based; or

(2) A certification, signed by the responsible official of the facility and supported by appropriate documentation, that there has been a material change in the factors upon which the certification was based.

(c) *Facilities certified under § 124.514.* A facility certified under § 124.514 shall comply with paragraph (a)(3) of this section and shall submit within 90 days after the close of its fiscal year, as appropriate:

(1)(i) A certification, signed by the responsible official of the facility, that there has been no material change in the factors upon which the certification was based; or

(ii) A certification, signed by the responsible official of the facility and supported by appropriate documentation, that there has been a material change in the factors upon which the certification was based; and

¹The addresses of the HHS Regional Offices are set out in 45 CFR 5.31.

(2) A certification, signed by the responsible official of the facility, of the amount of uncompensated services provided in the previous fiscal year.

(d) *Facilities certified under § 124.515.* A facility certified under § 124.515 shall submit such reports as are required by the terms of its grant under section 329 or 330 or by its agreement under section 334 of the Act, as applicable, at such intervals as the Secretary may require.

(Approved by the Office of Management and Budget under control number 0915–0077)

[52 FR 46031, Dec. 3, 1987, as amended at 52 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989; 59 FR 44639, Aug. 30, 1994]

§ 124.510 Record maintenance requirements.

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, or § 124.516.*

(1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance with the requirements of this subpart in any fiscal year, including:

(i) Any documents from which the information required to be reported under § 124.509(a) was obtained;

(ii) Accounts which clearly segregate uncompensated services from other accounts; and

(iii) Copies of written determinations of eligibility under § 124.507.

(2) A facility shall retain the records maintained pursuant to paragraph (a)(1) for three years after submission of the report required by § 124.509(a)(1), except where a longer period is required by the Secretary, or until 180 days following the close of the Secretary's assessment investigation under § 124.511(b), whichever is less.

(3) A facility shall, within 60 days of the end of each fiscal year, determine the amount of uncompensated services it provided in that fiscal year. Documents that support the facility's determination shall be made available to the public on request. If a report is or will be filed under § 124.509(a)(1), a facility may respond to a request by providing a copy of the report to the requester.

(b) *Facilities certified under § 124.513, § 124.514, or § 124.516.* A facility certified

under § 124.513, § 124.514, or § 124.516 shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance with the applicable requirements of this subpart in any fiscal year, including those documents submitted to the Secretary under § 124.513(c), § 124.514(c), or § 124.516(c). A facility shall maintain these records for three years, except where a longer period is required as a result of an investigation by the Secretary. In such cases, records must be kept until 180 days following the close of the Secretary's assessment investigation under § 124.511(b).

(c) *Facilities certified under § 124.515.* A facility certified under § 124.515 shall maintain the records required by its grant under section 329 or section 330 or its agreement under section 334 of the Act, as applicable, for such period of time as the grant agreement may require.

(Information collection requirements in paragraphs (a) and (b) approved by the Office of Management and Budget under control number 0915-0103)

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987; 59 FR 44639, Aug. 30, 1994]

§ 124.511 Investigation and determination of compliance.

(a) *Complaints.* A complaint that a facility is out of compliance with the requirements of this subpart may be filed with the Secretary by any person.

(1) A complaint is considered to be filed with the Secretary on the date the following information is received in the Office of the HHS Regional Health Administrator for the Region in which the facility is located:

(i) The name and address of the person making the complaint or on whose behalf the complaint is made;

(ii) The name and location of the facility;

(iii) The date or approximate date on which the event occurred; and

(iv) A statement of what actions the complainant considers to violate the requirements of this subpart.

(2) The Secretary promptly provides a copy of the complaint to the facility named in the complaint.

(3) When the Secretary investigates a facility, the facility, including a facility certified under § 124.513, § 124.514, § 124.515, or § 124.516, shall provide to the Secretary on request any documents, records and other information concerning its operation that relate to the requirements of this subpart. A facility will be presumed to be out of compliance with its assurance unless it supplies documentation sufficient to show compliance with the applicable provisions of this subpart.

(4) Section 1627 of the Act provides that if the Secretary dismisses a complaint or the Attorney General has not brought an action for compliance within six months from the date on which the complaint is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he/she will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, the Secretary may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the applicant, dismiss the complaint without a finding as to compliance prior to the end of the six month period, but no earlier than 45 days after the complaint is filed.

(b) *Assessments.* The Secretary periodically investigates and assesses facilities to ascertain compliance with the requirements of this subpart, including certification of the amount of uncompensated services provided in a fiscal year or years, and provides guidance and prescribes corrective action to correct noncompliance.

(1) *Compliance after February 1, 1988.*

(i) The Secretary may certify that a facility has substantially complied with its assurance for a fiscal year or years, and such certification shall establish that the facility provided the amount of uncompensated services certified for the period covered by the certification.

(ii) A certification of substantial compliance shall be based on the amount properly claimed by the facility pursuant to § 124.509(a), utilizing procedures determined by the Secretary to be sufficient to establish that the facility has substantially complied